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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/722,659	09/27/1996	D. CLARK BENNETT	104385.140	4359

7590

05/18/2004

HOLLIE L. BAKER  
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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	08/722,659		BENNETT ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	F. Pierre VanderVegt		1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application claims the benefit of the filing date of provisional application 60/004,622.

Claims 8-17 have been canceled.

Claims 1-7 and 18-19 are currently pending and are the subject of examination in the present Office Action.

#### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on January 26, 2004 has been entered.

2. In view of Applicant's amendment and the declarations of Richard Broughton, Israel Vlodavsky & Elizabeth Cauchon and the executed statement of Rita Charles filed January 26, 2004, the previous ground of rejection has been modified and is made NON-FINAL. Applicant's arguments and the declarations will be addressed as they pertain to the ground of rejection as set forth *infra*.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-7, 18 and 19 are rejected under 35 U.S.C. 102(e or f) as being anticipated by U.S. Patent No. 5,997,863 to Zimmerman et al (of record).

The applied reference has a common assignee and some common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Following the board decision mailed November 24, 2003, Applicant has amended the claim to recite that the subject is a "human" rather than a "patient." The '863 patent teaches a method of treating ischemia in a rabbit hind limb ischemic model by administering heparinase 1 (see column 17, line 62 through column 18, line 34 in particular). The '863 patent also teaches that administering heparinase removes heparin and heparan sulfate from cell surfaces and from the extracellular matrix, thereby facilitating the mobility of cytokines, chemoattractants and cells (see column 4, line 63 to column 5, line 19 in particular). The '863 patent teaches that the heparinase enzymes, including heparinase 3, are derived from *Flavobacterium heparinum* (column 6, lines 2-48 in particular) and the recombinant production of the enzymes (column 9, lines 37-64 in particular). The '863 patent teaches that heparin and heparan sulfate-degrading enzymes release chemokines (heparin binding growth factors) and heparan sulfate fragments from the extracellular matrix (column 6, lines 49-58 in particular). The '863 patent further teaches that wound healing is generally divided into three temporally overlapping phases: inflammation, proliferation and remodeling. During inflammation, blood borne cells infiltrate the wound site and release mediating factors (see column 2, lines 56-67 in particular). While the '863 patent exemplifies the treatment of a rabbit in a model study, there is a clear conception of the treatment of human subjects, as the '863 patent further teaches that compositions comprising one or more of the enzymes have potential utility for the treatment of humans (column 18, lines 26-29 in particular). The instant specification on page 39 discloses that ischemia induces inflammatory responses such as migration

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of neutrophils across the connective tissue, extravasation of plasma and other blood and cellular components. Therefore, the method of treating ischemia by administering heparinase taught by the '863 patent would also decrease the localized inflammatory responses that result from ischemia. Thus, the methods of the '863 patent anticipate the instantly claimed method of decreasing localized inflammatory responses.

The declarations under 37 CFR § 1.132 of Richard Broughton, Israel Vlodavsky and Elizabeth Cauchon filed January 26, 2004 have been fully considered in regard to the ground of rejection. The Broughton and Vlodavsky, who are co-inventors of the '863 patent but are not co-inventors of the present application, declarations establish that they did not contribute to the portions of the '863 patent that form the basis for the instant ground of rejection.

The declaration of Elizabeth Cauchon, who is named as a co-inventor of the present application but is not a co-inventor of the '863 patent, does not serve to clarify the inventorship of the claimed invention. Ms. Cauchon declares that she is a co-inventor of the present application. She further declares that she made no inventive contribution to the portions of the '863 patent that form the basis for the instant ground of rejection. Because the '863 patent constitutes an anticipatory reference for all of the instant claims, it is unclear what inventive contribution she made to the presently claimed invention, which appears to be solely the work of Clark Bennett and Pamela Danagher. Applicant is requested to clarify what contributions Elizabeth Cauchon made to the instantly claimed invention or to amend the inventorship of the present application accordingly.

### *Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
May 13, 2004

  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER

5/17/04